Attachment D Journal Information Piece for Dermatologists

Important Information for Dermatologists about the Potential Risks of Serious Infections, Malignancy, and RPLS with STELARA® For Psoriasis and Psoriatic Arthritis Therapy

STELARA® (ustekinumab) is a human monoclonal antibody that is indicated for the following:

- treatment of adult patients (18 years or older) with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy
- treatment of adult patients with active psoriatic arthritis (alone or in combination with methotrexate).

STELARA® targets interleukin-12 (IL-12) and interleukin-23 (IL-23). Based on data from rodent models and humans genetically deficient for components of IL-12 and IL-23 pathways, there is a theoretical concern that **blockade of IL-12 and IL-23 may increase the risk for serious infections, including mycobacterial and recurrent salmonella infections.** In addition, data from rodent models suggest there is a theoretical concern that **blockade of IL-12 and IL-23 may increase the risk for malignancies**.

One case of Reversible Posterior Leukoencephalopathy Syndrome (RPLS) has been reported in a STELARA®-treated patient in clinical trials. RPLS is a neurological disorder which is not caused by demyelination or a known infectious agent, and can present with headache, seizures, confusion and visual disturbances.

If you have a patient that develops a serious infection or RPLS while being treated with STELARA®, or if you have a patient with cancer at any time after receiving STELARA® therapy, it is important that you report the case even if you do not think there is a causal relationship.

The information that you, as a STELARA® prescribing dermatologist, can provide may inform therapy and monitoring decisions for psoriasis patients.

Reporting is easy and maintains patient confidentiality. Your patient's name or contact information is not needed. *HIPAA does not apply to* this adverse event reporting.

You can report your cases to the STELARA® manufacturer or directly to FDA.

- Janssen Biotech, Inc. at 1-800-526-7736
- MedWatch (FDA safety information and adverse event reporting program) at 1-800-332-1088 or online at www.fda.gov/medwatch/report.htm

PSOLAR (Psoriasis Longitudinal Assessment and Registry): is a **voluntary, disease specific registry,** developed by Janssen Biotech, Inc. that collects information from psoriasis patients and their treating physicians. Since this registry will continue for 10 years, it will help us better understand the risk of long-latency serious events, such as malignancies, that can occur after exposure to a product such as STELARA®.

For more information on PSOLAR and how to include patients in this voluntary registry, call 1-888-PSOLAR5 (1-888-776-5275) or access www.clinicaltrials.gov and search for PSOLAR.